

United States Senate

WASHINGTON, DC 20510

October 9, 2014

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg,

Media reports have recently highlighted that in the absence of a clear federal standard, e-cigarette manufacturers owned by big tobacco companies are beginning to concoct their own health warnings about their products that lack uniformity and are not comprehensive in listing all of the health threats the products pose.

These reports underscore the need to finalize within a year of its release the “deeming regulation” the Food and Drug Administration (FDA) proposed on April 24, 2014 to begin to regulate e-cigarettes under authority granted by the Family Smoking Prevention and Tobacco Control Act. We further urge the FDA to adopt aggressive warning labels that correctly communicate the health consequences of e-cigarette use and to take this opportunity to review and update warning labels for all tobacco products, including those that have long been on the market, to ensure that consumers are aware of their risks.

Examples of these new warning labels, illustrated by *The New York Times* on September 28, include one from Reynolds American that states that their product is not intended for those “who have an unstable heart condition, high blood pressure, or diabetes; or persons who are at risk for heart disease or are taking medicine for depression or asthma.” Yet another warning label from Altria states, “Nicotine is addictive and habit forming, and is very toxic by inhalation, in contact with the skin, or if swallowed.”

These two examples show the lack of uniformity of information across companies and highlight how voluntary health warnings often leave out known dangers from nicotine use – such as risks to adolescent brain development and pregnant women, as well as the dangers posed by additives and other chemicals that may be in e-cigarettes, such as benzene and formaldehyde.

We urge the FDA to pursue standardized consumer protections that are strictly based on scientific evidence. In FDA’s proposed “deeming regulation,” the agency includes a warning label for e-cigarettes that does not adequately warn consumers on the known dangers of nicotine use. The proposed label reads “WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.” We support requiring a label on nicotine’s addictive properties, but we ask the FDA pursue requirements for more extensive warnings that address health risks that e-cigarettes pose.

Please respond with details about the actions the FDA is taking to require e-cigarette manufacturers to truly disclose the risks their products pose to consumers.

Sincerely,



Barbara Boxer
United States Senator



Richard J. Durbin
United States Senator



Richard Blumenthal
United States Senator



Jack Reed
United States Senator



Sherrod Brown
United States Senator



Edward J. Markey
United States Senator

CC: The Honorable Sylvia Mathews Burwell, Secretary of the Department of Health and Human Services